FEDERAL RAILROAD ADMINISTRATION
POST-ACCIDENT LABORATORY PROCUREMENT
ON-SITE AUDIT PROTOCOL
FOR
DTFR53-02-R-00003

Laboratories selected for on-site audit will be rated by the FRA's Technical Oversight Contractor in each of the categories and sub-categories described in the attached protocol. The Technical Oversight Audit Team will award each laboratory a total raw score, with individual scores granted for each sub-category based on a graduated rating scale (scales not included here). Audit categories and sub-categories directly support (but are secondary to) the evaluation criteria set forth in Section M of the RFP.

The Technical Oversight Contractor's Audit Team will be made up of up to three inspectors, including a Team Leader who will have overall responsibility for the performance of the audit and the evaluation of the laboratory. At least two members of the Audit Team are to be forensic toxicologists holding diplomate status (DABFT). The audit is designed to be conducted over a single day.

Once all of the on-site audits have been completed, the Technical Oversight Contractor will provide FRA a comprehensive report (or individual reports) which will evaluate the laboratories in every audited category. The raw score given each laboratory by the Technical Oversight Team in the on-site audit will be multiplied by a conversion factor to arrive at a cumulative point total based on a possible maximum audit award. As specified in the RFP's Technical Evaluation Plan, each laboratory's audit points will then be added to the points granted their Technical Proposal in order to determine a final grand total score.

ON-SITE LABORATORY AUDIT PROTOCOL

I. Lab Qualifications

A. The laboratory will be asked to demonstrate that it holds the required licenses/certifications for their jurisdiction and this contract (DHHS/SAMHSA).

II. Laboratory Capability and/or Experience

A. The laboratory's capability in urine, blood, and tissue be rated.

B. The laboratory's experience in urine, blood, and tissue be rated.

III. Staffing

A. The quality of the senior management personnel who are likely to have direct hands-on with the FRA contract will be rated. Included in the evaluation will be senior supervisors and personnel who will certify FRA data.

B. The quality of bench analysts, data reviewers, and quality control personnel who are likely to have hands-on with the FRA contract will be rated.

C. The quality of the receiver/accessioners and other support personnel (i.e., data entry, clerical, etc.) who are likely to have hands-on with the FRA contract will be rated.

D. The quality of personnel who are likely to advise the FRA on the significance of analytical data in the determination of accident/incident cause will be rated. These personnel are expected to have advanced capability in the pharmacology, physiological and psychological effects, pharmacokinetics, and pharmacodynamics of the substances of interest.

E. The quality of personnel who are likely to provide expert witness testimony on behalf of FRA cases will be rated.

F. The quality and applicability of the internal and external training programs for laboratory personnel likely to be involved in the FRA contract will be rated.

G. The staffing of Laboratory will be evaluated. Staff levels versus workload, and staff organization (i.e., shift structure) versus expected turn-around-time (TAT) will be examined.

IV. Analytical Methods

A. The quality of receiving, accessioning, aliquoting, and internal chain-of-custody protocols will be evaluated. Special focus will be placed on experience in blood aliquoting procedures and techniques.

B. The quality of any comparable SOPs and related bench practices to screen by immunoassay in urine, blood, and tissue will be evaluated.

C. The quality of any comparable SOPs and related bench practices for extraction and other sample preparation requirements for confirmation in urine, blood, and tissue will be evaluated. Recent batch acceptance rates for individual extractors may be examined.

D. The quality of any comparable SOPs and related bench practices for confirmation by GC/MS in urine, blood, and tissue will be evaluated.

Note: FRA recognizes that some laboratories may not have existing SOPs or bench practices for the Audit Team to evaluate. In that case, the Audit Team will investigate each area through oral interviews with appropriate laboratory personnel. Blood cannabinoid, cocaine, and benzodiazepine procedures will receive special attention. The intent of this portion of the audit is to help determine whether the laboratory will be able to detect the required analytes down to the sensitivities required by the FRA contract. Quality control data will be reviewed as necessary.

V. Quality Control/Quality Assurance

A The overall laboratory quality assurance program will be reviewed. The commitment of the laboratory to practices which ensure the accuracy, precision, and scientific defensibility of the results will be examined.

B. Retained internal quality control data will be reviewed. The Audit Team will examine at least the following questions: Are trends and biases monitored appropriately and remedial actions correctly taken? Are quality control materials extended appropriately and are expired materials efficiently removed from service? Are materials properly prepared and certified? Are LOQs, LODs, and LOLs properly determined?

C. The results of external quality control programs will be reviewed. The Audit Team will examine at least the following questions: Does the laboratory regularly participate in national proficiency testing programs such as SAMHSA or CAP, and/or state programs? Does the laboratory perform acceptably? When problems occur, are they aggressively pursued and appropriate remedial action(s) taken?

D. The laboratory will be asked if it has produced a false positive or false negative result in the last two years. If answered yes, the root cause(s) of the problem and the remedial action taken by the laboratory will be evaluated to ensure that similar error(s) could not reoccur.

E. The quality of any comparable data review SOPs and laboratory practices will be evaluated to ensure that adequate safeguards exist for the proper review and accurate reporting of data.

VI. Equipment and Facilities

A. The principal analytical equipment likely to be utilized in FRA testing will be evaluated. This will include technologies employed for screening, extractions, and confirmation. The Audit Team will attempt to determine whether the quantity of equipment is sufficient and the quality of the equipment is acceptable to properly analyze FRA specimens.

B. Operation and maintenance logs and tuning and calibration records will be evaluated. The Audit Team will examine whether these records give confidence that equipment likely to be utilized in FRA testing performs accurately with acceptable levels of downtime.

C. The quality and performance of analytical support equipment, including pipets, balances, refrigerators, etc., will be evaluated.

D The physical plant of the laboratory will be evaluated. The Audit Team will examine at least the following questions: Do specimens appear to flow smoothly through the laboratory? Are spaces arranged in a manner to facilitate management of data, and the proper maintenance of equipment?

E. The security of the facility will be evaluated. Access points, logs, and all other systems designed to protect the laboratory, FRA records, and FRA specimens will be examined. Data and specimen storage will also be evaluated. The adequacy of facilities to maintain the integrity of FRA records and specimens will be examined.